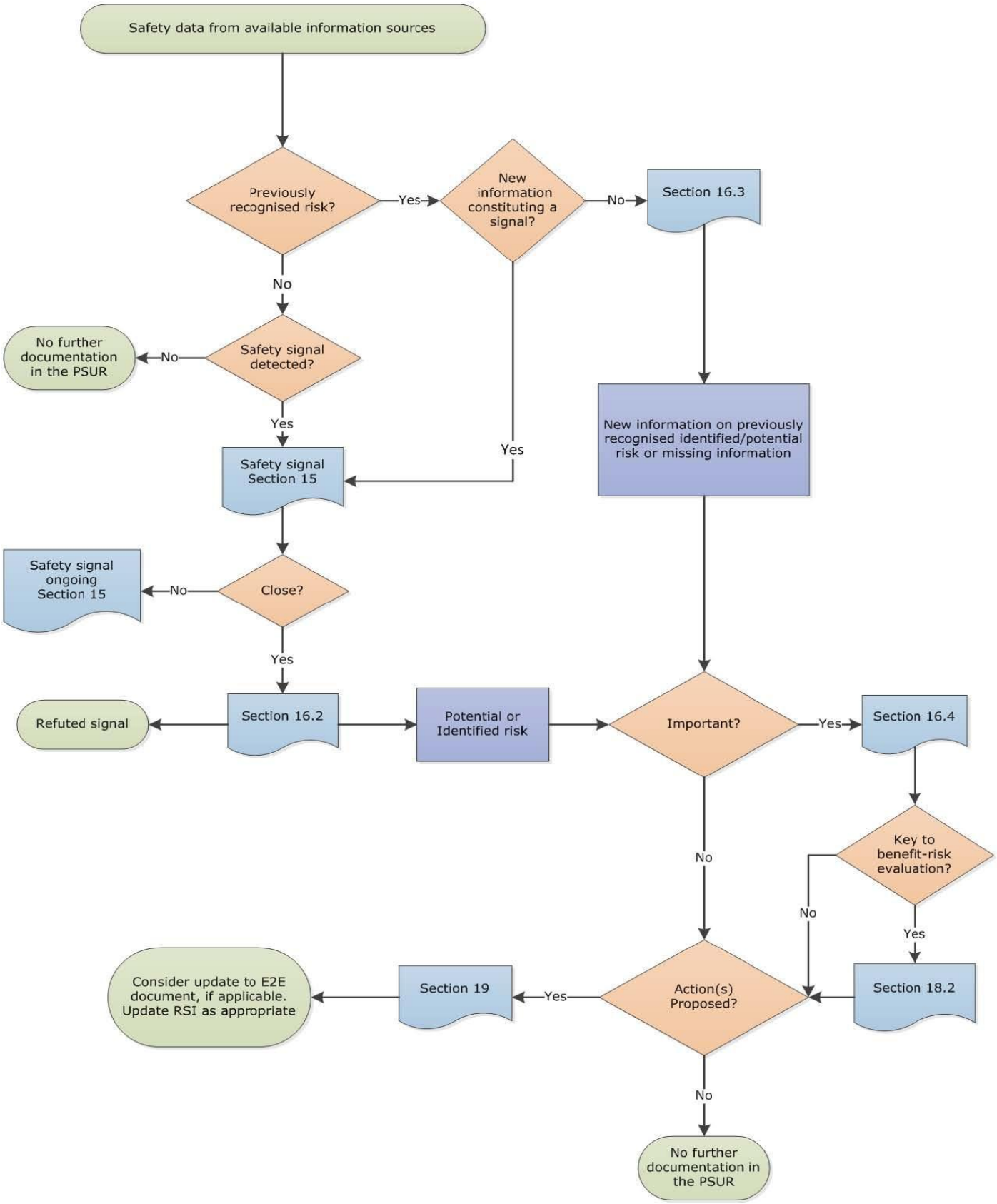
Safety data from available information sources
Previously recognised risk?
Yes
New information constituting a signal?
No
Section 16.3
No
No further documentation in the PSUR
No
Safety signal detected?
Yes
Yes
New information on previously recognised identified/potential risk or missing information
Safety signal Section 15
Safety signal ongoing Section 15
No
Close?
Yes
Refuted signal
Section 16.2
Potential or Identified risk
Important?
Yes
Section 16.4
No
Key to benefit-risk evaluation?
No
Yes
Consider update to E2E document, if applicable. Update RSI as appropriate
Section 19
Yes
Action(s) Proposed?
Section 18.2
No
No further documentation in the PSUR